

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)(KMW) <i>REDACTED VERSION</i>

**PLAINTIFFS' *DAUBERT*
MOTION TO EXCLUDE TESTIMONY OF DEFENDANTS' CLASS
CERTIFICATION EXPERT LAUREN J. STIROH, PH.D.**

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I. INTRODUCTION

While Dr. Lauren J. Stiroh may be a qualified economist, the class certification opinions she proffers here are premised on a fatally flawed hypothetical that does not derive from an acceptable methodology, and must be excluded as unreliable, unreliably applied, contrary to the law and facts (both of which she ignores), and unhelpful. In her Expert Report, Dr. Stiroh discusses

[REDACTED]

this discussion is the basis for her critique of Dr. Rena Conti's Declaration submitted by Plaintiffs in support of Class Certification. As part of this fanciful analysis, Dr. Stiroh professes [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Two critical flaws preclude admission of these opinions.

First, consumers *cannot* purchase adulterated drugs in the United States. *See, e.g.*, 21 U.S.C §§ 331, 351. Federal law prohibits the sale of adulterated drugs in the United States. Moreover, to a person, every Retail Pharmacy Defendant's corporate designee testified that [REDACTED]

[REDACTED]. The world Dr. Stiroh posits is [REDACTED]

[REDACTED]

[REDACTED].¹ Dr. Stiroh's disregard for the law (federal law and analogous state law banning sale of adulterated drugs) as well as the facts of this case (e.g., the undisputed

¹ The short period of time after discovery of the NDMA and NDEA impurities, during which the FDA advised patients not to abruptly cease their medication and risk heart attacks, strokes, and other catastrophic cardiovascular events, until their doctors prescribed replacement medications is not of any help to Dr. Stiroh for obvious reasons, and even if it were then that analysis would only apply to the few weeks before the complete recall was imposed.

corporate testimony that [REDACTED]
[REDACTED]) renders her methodology unacceptable, and opinions unreliable, contrary to the law and facts, and unhelpful.

Second, Dr. Stiroh's opinions rely upon some [REDACTED]
[REDACTED]. However, she herself concedes that the notion of [REDACTED]

[REDACTED] Dr. Stiroh also concedes that [REDACTED]
[REDACTED]. And while she criticizes Dr. Conti for [REDACTED]

[REDACTED]. Were this not enough, with respect to her recitation regarding the [REDACTED]
[REDACTED], Dr. Stiroh admits that she did not consider the undisputed law or facts in this case that [REDACTED]. Of course, Dr. Stiroh's

disregard for this factual reality is by design, and renders her opinions improper net opinions. Dr. Stiroh recognizes that had she considered the [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

For these reasons, discussed more fully below, Dr. Stiroh's proposed class certification opinions on [REDACTED] should be excluded.

II. APPLICABLE LAW

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence 702. The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco*,

Inc., 186 F.3d 412, 417-18 (3d Cir. 1999).

As a threshold matter, Rule 702 “requires the witness to have ‘specialized knowledge’ regarding the area of testimony” proffered by the witness. *Waldorf v. Shuta*, 142 F.3d 601 (3d Cir. 1998). Once qualified, an “expert’s opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation.” *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 742 (3d Cir. 1994) (citations and internal quotations omitted). Thus, “the expert must have ‘good grounds’ for his or her belief.” *Id.* (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the analysis and, “any step that renders the analysis unreliable under the *Daubert* factors renders the expert’s testimony inadmissible.” *Id.* at 745. Judges within this Circuit also consider how and when the methodology is used outside of litigation. *Paoli*, 35 F.3d at 742 (discussing reliability factors under *Daubert* and Third Circuit case law).

Importantly, the Third Circuit has held that “[i]t is an abuse of discretion to admit expert testimony which is based on assumptions lacking any factual foundation in the record.” *Steyck v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) (citing *Elcock v. Kmart Corp.*, 233 F.3d 734, 756 & n.13 (3d Cir. 2000)).

Furthermore, “*Daubert’s* gatekeeping requirement . . . make[s] certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)); see also *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F.Supp.2d 584, 594 (D.N.J.2002), *aff’d*, 68 Fed. Appx. 356 (3d Cir. 2003).

III. ARGUMENT

A. Dr. Stiroh's Opinions that [REDACTED] Are Unreliable, Unreliably Applied, Unsupported, and Unhelpful

The centerpiece of Dr. Stiroh's critique of Plaintiffs' and their expert's, Dr. Conti's, economic modeling of class-wide damages is that, [REDACTED].² But Dr. Stiroh's critique rests on an unacceptable methodology built on two faulty premises, either of which warrants exclusion of her opinions.

First, she opines [REDACTED]

[REDACTED]³ But this premise is at odds with the facts in this case. [REDACTED]

[REDACTED]. This fact is undisputed.⁴ Thus, the real-world facts completely undercut Dr. Stiroh's baseless assumption that

[REDACTED]⁵

² See, e.g., Ex. 1 at ¶¶ 7, 20, 30, 33, 35.

³ See, e.g., Ex. 1 at ¶ 7.ii.

⁴ See, e.g., Ex. 2 at 167:4-168:1; Ex. 1 at ¶ 21 ([REDACTED]). Defendants themselves have claimed early and often in this litigation that the presence of NDMA/NDEA in their VCDs was not known and could not have been known to them, most recently in their opposition papers to class certification. While Plaintiffs take issue with these claims, and will prove constructive and/or actual knowledge at a merits stage of this case, in light of these assertions, Defendants cannot argue that consumers (and reimbursing TPPs) would be in a better position to acquire knowledge than Defendants themselves.

⁵ Dr. Stiroh also ignores the fact that [REDACTED]. Generic drugs are not ordinary over-the-counter household items. Doctors prescribe consumers a drug, and a pharmacy chooses which generic drug (that is supposed to be

Second, in an effort to get around the fact that [REDACTED]

[REDACTED]

[REDACTED].⁶ Within the confines of this alternative reality, Dr. Stiroh opines that [REDACTED]

[REDACTED]

[REDACTED]⁷ Putting aside the stunning implausibility of this hypothetical,⁸ Dr. Stiroh ignores the law and fact that [REDACTED]
[REDACTED]. She also ignores the testimony of Defendants' corporate representatives, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]"¹⁰

Dr. Stiroh admits [REDACTED]

[REDACTED]"¹¹ She did not [REDACTED]

the same as the branded drug) to dispense. Neither Defendants nor Dr. Stiroh posit, let alone cite, any situation in which [REDACTED]
[REDACTED] as if it were a pack of gum, especially where the point of decision is [REDACTED]
[REDACTED].

⁶ See, e.g., Ex. 1 at 7.ii.

⁷ *Id.*

⁸ See *supra* note 4.

⁹ Ex. 6 ([REDACTED]) at 84:5-10, 325:18-326:1.

¹⁰ *Id.*

¹¹ Ex. 2 at 42:9-43:2 [REDACTED]; *id.* at 147:18-148:13

[REDACTED].").

[REDACTED]¹² *See, e.g.*, 21 U.S.C

§§ 331, 351. Even though she did not look to [REDACTED]

[REDACTED]¹³ She also did not read (let alone rely on) [REDACTED]

[REDACTED]¹⁵

¹² Ex. 2 at 173:4 - 173:17 (“

¹⁴ Ex. 1 at Stiroh Rpt. Ex. 2 (reliance materials).

¹⁵ *See, e.g.*, Ex. 3 at 32:4 – 33:9 (“

Expert testimony that is contrary to law or fact, or that seeks to misstate the applicable law to the jury, is unhelpful. *See, e.g., SEC v. Ambassador Advisors, LLC*, -- F. Supp. 3d --, *5 (E.D. Pa. Dec. 21, 2021). Expert analysis also must have sufficient support in facts or data for the conclusions reached. *See, e.g., Mondis Tech. Ltd. v. LG Elecs., Inc.*, No. 15-4431, 2021 WL 4077563, at *3 (D.N.J. Sept. 8, 2021). An expert's damages opinion is inadmissible if it "is both contrary to the record...[and] is contrary to the law." *See, e.g., Apotex, Inc. v. Cephalon, Inc.*, 321 F.R.D. 220, 236 (E.D. Pa. 2017). Opinions that rest on "assumptions and conclusions that are not supported by the factual record" have been excluded on the basis that they would not "aid the jury in resolving a factual dispute" because they do not "fit under the facts of the case." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 790 (3d Cir. 2009) (internal citations and quotations omitted).

Here, Dr. Stiroh states and relies on an inadequate hypothetical that misstates the real-world facts about [REDACTED]. Her attempt to compensate this through a counter-factual world in which [REDACTED] [REDACTED] [REDACTED] [REDACTED]. Thus, Dr Stiroh's opinions that [REDACTED] [REDACTED] must be excluded. *See, e.g., Steyck*, 295 F.3d at 414 ("It is an abuse of discretion to admit expert testimony which is based on assumptions lacking any factual foundation in the record.").

[REDACTED]

**B. Dr. Stiroh's Opinions About [REDACTED]
[REDACTED] Are Unreliable and Do Not Fit the Facts of This Case**

Dr. Stiroh asserts [REDACTED]

[REDACTED]¹⁶ By [REDACTED].¹⁷ Yet, she also acknowledges [REDACTED]

[REDACTED]¹⁸ That is, Dr. Stiroh admits that [REDACTED]
[REDACTED]. She therefore admits that the premise of her critique of Dr. Conti concerning the need to take into account [REDACTED]

[REDACTED] Her opinion is excludable for this reason as well.

So, too, are her opinions about [REDACTED]
[REDACTED]. Consumer Economic Loss Plaintiffs allege, like the TPP Plaintiffs, that they suffered economic harm at the point of sale. Dr. Stiroh [REDACTED].¹⁹ Instead, she posits that one must [REDACTED]

[REDACTED]²⁰ But, as discussed *supra* Part III.A, one cannot [REDACTED]

¹⁶ Ex. 2 at 66:4-17.

¹⁷ *Id.* at 67:1-3.

¹⁸ *Id.* at 67:4-10.

¹⁹ *Id.* at 127:8-20 (“[REDACTED]”)

²⁰ See, e.g., Ex. 2 at 43:3-22.

[REDACTED]. Further, Dr. Stiroh herself proffers no method, let alone reliably applies one, for [REDACTED].”²¹

IV. CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Stiroh’s opinions as set forth *supra* Parts III.A-B.

Dated: May 3, 2022

Respectfully,

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On Behalf of MDL PEC and Class Plaintiffs

²¹ Ex. 2 at 71:3-10 ([REDACTED])

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 3, 2022, a true and correct redacted copy of the foregoing was filed and served via the court's CM/ECF system, and an unredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch

David J. Stanoch